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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/523,000	11/18/2005	Neil David Watkins	1781-0016	4665
28/078 7590 04/07/2008 MAGINOT, MOORE & BECK, LLP CHASE TOWER 111 MONUMENT CIRCLE SUITE 3250 INDIANAPOLIS, IN 46204				
EXAMINER				
SKOLER, JAY R				
ART UNIT		PAPER NUMBER		
3733				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/523,000

Applicant(s)

WATKINS ET AL.

Examiner

JAY R. SIGLER

Art Unit

3733

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 January 2008.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-8 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 28 January 2008 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/5508)
Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 2 and 3 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In claim 2, the language "in which a further pressure sensor is located in a least one of..." is considered new matter. While the disclosure allows for a sensor to be placed in several different locations and two sensors to be placed in the sealing component, seen in Fig. 2 and 3b, the disclosure is not considered to reasonably convey that a sensor can be placed in the sealing component and an additional sensor can be placed in one of the other locations. Claim 3 also includes a further pressure sensor.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown et al. (U.S. Patent 5,842,785) in view of Cohen et al. (U.S. Patent 5,980,527), Draenert (U.S. Patent 4,671,263), and EP 0 444 842 A2 (EP '842, cited by applicant).

a. Concerning claim 1, Brown et al. teaches an instrument (Figure 1 and 4) for deploying a bone cement material in a bone cavity, the instrument comprising: a chamber 1 in which the components of the material can be mixed; a mixing tool 5 which extends into the chamber, and which can be manipulated from outside the chamber, to cause the components of the material to mix (Column 5, Lines 48-50); an outlet (at the end of part 1 where the nozzle 12 is attached) from the chamber through which the mixed material can be discharged from the chamber after it has mixed; a piston 3 which can be moved through the chamber to apply positive pressure to mixed material within the chamber, to displace the mixed material from the chamber through the outlet into a bone cavity (Column 5, Lines 12-15).

Brown et al. probably does not teach a sealing component which fits over the bone cavity or a sensor which is placed in the sealing component.

Cohen et al. teaches a sealing component (Figure 1), to be used with a device for adding bone cement to a bone cavity (Column 5, lines 19-22), which fits over a bone cavity to allow the pressure to be maintained on the cement throughout the period in which it hardens, as preferred for secure bonding of the cement to the bone (Column 6, Lines 60-63). It would have been obvious to someone of ordinary skill in the art at the time of the invention to use the sealing

component of Cohen et al. with the invention of Brown et al. to allow the pressure to be maintained on the cement throughout the period in which it hardens, as preferred for secure bonding of the cement to the bone.

Draenert teaches a device for applying bone cement that includes a sensor (Column 5, Lines 41-44; taken to be embodied by a pressure gauge) to control the pressure during application (Column 5, Lines 41-44). It further would have been obvious to someone of ordinary skill in the art at the time of the invention to add a sensor to the modified invention of Brown et al., in view of Cohen et al. and Draenert, to control the pressure during application.

EP '842 suggests placing a pressure sensor in a sealing component (see Fig. 1) in order to control the pressure applied to the bone cement in the bone canal (col. 3, ll. 14-17; Fig. 1). It would have been obvious to someone of ordinary skill in the art at the time of the invention to place a the sensor in the sealing component, in view of EP '842, in the modified invention of Brown et al., in view of Cohen et al. and Draenert, in order to control the pressure applied to the bone cement in the bone canal. Alternatively, it would have been at least obvious to try placing a sensor in the sealing component in the modified invention of Brown et al., in view of Cohen et al., Draenert, and EP '842, because a person of ordinary skill has good reason to pursue the known options within his or her technical grasp, i.e. locating the sensor in the sealing cap, chamber, piston or outlet from the chamber.

- b. Concerning claim 2, Brown et al., in view of Cohen et al., Draenert, and EP '842, fairly suggests the claimed invention including locations for a sensor being in the chamber (see Draenert: Column 5, Lines 41-44; taken to be embodied by the pressurized zone) or on the piston (see Draenert: Column 5, Lines 48-50), but does not specifically suggest having two sensors. Adding an additional sensor is considered a mere duplication of parts. It would have been obvious to one having ordinary skill in the art at the time the invention was made to add an additional sensor to the modified invention of Brown et al., in view of Cohen et al., Draenert, and EP '842, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.
- c. Concerning claim 3, the additional pressure sensor would be close to any face of the sealing component in the modified invention of Brown et al., in view of Cohen et al., Draenert, and EP '842. The definition of close being taken as being near in space (close. 2003. In *The American Heritage® Dictionary of the English Language*. Retrieved September 18, 2007, from <http://www.credoreference.com/entry/4074086>).
- d. Concerning claim 4 and 5, Cohen et al. further teaches the sealing component comprises: a sealing plate which can be fitted over the bone cavity and has a quantity of a resiliently deformable material on its lower face to enable a seal to be created between the plate and the edge of the bone (Claim 1); and a plug which has an injection port extending through it in which the outlet (Claim 1,

taken to be embodied by the injection nozzle of bone cement delivery apparatus) can be received, the sealing plate having an opening extending through it in which the plug can be received, and through which a prosthesis which is to be bonded to the bone of the cavity by the bone cement can be inserted into the cavity after injection of the cement and removal of the plug (Claim 1).

e. Concerning claim 6, Draenert further teaches the pressure sensor generates a signal which is representative of the pressure to which the bone cement is subjected during displacement from the chamber, and in which the signal gives rise to an indication of the said pressure which is visible (Column 5, Lines 46-47 and Column 12, Lines 49-53; taken to be embodied by the color rings indicate the existing pressure and the pressure is adjusted manually to the desired value indicated by a color marking of the pressure gauge).

f. Concerning claim 7, Brown et al., in view of Cohen et al., Draenert, and EP '842, fairly suggest the claimed invention as shown above including causing a warning signal to be generated indicating the pressure, but does not specifically suggests the range of less than about 3 kPa. It would have been obvious to one having ordinary skill in the art at the time the invention was made to signal when the pressure to which the bone cement is subjected during displacement from the chamber is less than about 3 kPa in the modified invention of Brown et al., in view of Cohen et al., Draenert, and EP '842, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the

optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

g. Concerning claim 8, Draenert also teaches the pressure sensor generates a signal which is representative of the pressure to which the bone cement is subjected during displacement from the chamber (as shown above), and in which the signal can be arranged to cause the pressure that is applied to the bone cement by the piston to be changed when the pressure is outside a pre-determined range (Column 5, Lines 46-48 and Column 12, Lines 49-53; taken to be embodied by the color markings for the correct pressure to be a pre-determined, or desired, range and that they would cause an operator to manually change the pressure when outside this range).

Response to Arguments

3. Applicant's arguments with respect to claims 1-8 have been considered but are moot in view of the new ground(s) of rejection.

Allowable Subject Matter

4. The indicated allowability of claims 5 and 7 is withdrawn in view of the new interpretation of the prior art.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAY R. SIGLER whose telephone number is (571)270-3647. The examiner can normally be reached on Monday through Thursday from 8 AM to 4 PM (EST).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. R. S./
Examiner, Art Unit 3733
/Eduardo C. Robert/
Supervisory Patent Examiner, Art Unit 3733